

K133593 T:SLIM INSULIN DELIVERY SYSTEMMar 24, 2014
122 days to decisionK133593 · Product code: **LZG** · General Hospital
Source: <https://www.510kdatabase.net/k133593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion, Insulin (LZG)
Date received	Nov 22, 2013
Decision date	Mar 24, 2014
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tandem Diabetes Care, Inc.
Location	San Diego, CA, US
Contact	JOHN SHERIDAN
510(k) history	25 submissions · 23 cleared · 2011-2026

Tandem Diabetes Care, Inc. is an American medical device manufacturer based in San Diego, California. The company develops medical technologies for insulin infusion therapy and diabetes treatment. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2011. Chemistry devices represent the dominant category of its regulatory portfolio. The latest FDA 510(k) clearance was granted in 2025, reflecting continued active development and regulatory engagement. Recent cleared devices include the Tandem Mobi insulin pump with interoperabl...

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